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PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of

Odile LETOURNEUR

Group Art Unit: 1642

Application No.: 10/526,765

Examiner: B. PENG

Filed: March 7, 2005

Docket No.: 122802

For: CHIMERIC RECOMBINANT PROTEIN AND IN VITRO DIAGNOSIS

RESPONSE TO ELECTION OF SPECIES REQUIREMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In reply to the June 20, 2007 Election of Species Requirement, Applicants provide the following response.

I. Election of Species Requirement

The Office Action requires Applicants to elect one recombinant DNA that consists of one specific combination of first, second and third nucleotide fragments by SEQ ID NOs: from claims 2, 4, and 6.

In response, Applicants provisionally elect SEQ ID NO:51 as a Species of a recombinant DNA as recited in claim 1, with traverse. For the Examiner's information, SEQ ID NO:51 comprises SEQ ID NOs:21, 27, 29, 31, 35, 37, and 39. Claims 1-13 read on the elected species. At least claim 1 is generic to all species.

The Office Action further requires Applicants to elect one linking region sequence and one attaching region sequence by SEQ ID NOs: from claims 9 and 12. In response, Applicants provisionally elect as a linking region sequence SEQ ID NO:36 and as an

attachment region sequence SEQ ID NO:38, with traverse. At least claims 7–13 read on the elected species. At least claim 7 is generic to all species.

National stage applications filed under 35 U.S.C. §371 are subject to unity of invention practice as set forth in PCT Rule 13, and are not subject to U.S. restriction practice. See MPEP §1893.03(d). PCT Rule 13.1 provides that an "international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept." PCT Rule 13.2 states:

Where a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

A lack of unity of invention may be apparent "*a priori*," that is, before considering the claims in relation to any prior art, or may only become apparent "*a posteriori*," that is, after taking the prior art into consideration. See MPEP §1850(II), quoting *International Search and Preliminary Examination Guidelines* ("ISPE") 10.03. Lack of *a priori* unity of invention only exists if there is no subject matter common to all claims. *Id.* If *a priori* unity of invention exists between the claims, or, in other words, if there is subject matter common to all the claims, a lack of unity of invention may only be established *a posteriori* by showing that the common subject matter does not define a contribution over the prior art. *Id.*

Furthermore, unity of invention only needs to be determined in the first place between independent claims, and not the dependent claims, as stated in ISPE 10.06:

Unity of invention has to be considered in the first place only in relation to the independent claims in an international application and not the dependent claims. By "dependent" claim is meant a claim which contains all the features of one or more other claims and contains a reference, preferably at the beginning, to the other

claim or claims and then states the additional features claimed (Rule 6.4).

See also MPEP §1850(II). ISPE 10.07 further provides:

If the independent claims avoid the prior art and satisfy the requirement of unity of invention, no problem of lack of unity arises in respect of any claims that depend on the independent claims. In particular, it does not matter if a dependent claim itself contains a further invention.

See also MPEP §1850(II).

Claim 1 is the only independent claim. Because claims 2–13 variously depend from claim 1, each of claims 2–13 contains each and every feature of claim 1. Accordingly, all the claims share common subject matter and, therefore, *a priori* unity of invention exists between all the claims. Thus, for the present application, a lack of unity of invention may only be determined *a posteriori*, or in other words, after a search of the prior art has been conducted and it is established that all the elements of the independent claim are known. *See* ISPE 10.07 and 10.08.

The Office Action does not establish that each and every element of the subject matter that is common to independent claim 1 is known in the prior art. Because the Office Action fails to apply any prior art, the Office Action fails to make a *prima facie* case of lack of unity of invention. Therefore, Applicants respectfully submit that lack of unity of invention has not been established, and thus a restriction requirement based on a lack of unity of invention is improper. Accordingly, the election of species requirement is improper and must be withdrawn.

Moreover, the Office Action has applied the incorrect standard in requiring an election between species. Although unity of invention practice under PCT Rule 13 recognizes that alternate forms of an invention may be present in separate independent claims, or in a single claim, restriction between distinct embodiments of a single claim may only be required if

there is a lack of unity of invention in that claim, or, in other words, the distinct embodiments share no common subject matter that defines a contribution over the prior art. *See* ISPE 10.09; MPEP §1250(II). The "patentably distinct species" standard, as applied under U.S. restriction practice, is not applicable to the current claims. Furthermore, the Office Action fails to establish that the "patentably distinct species" lack *a posteriori* unity of invention. Accordingly, the election of species requirement is improper and must be withdrawn.

Furthermore, Applicants traverse the election of species requirement on the ground that the generic claims are not so broad as to place an undue burden on the Patent Office to search and examine the full scope of the claims. Rather, Applicants respectfully assert that search and examination of the entire application could be conducted without undue burden on the Examiner, thus avoiding delay and expense to Applicants.

Applicants further understand, however, that upon search, examination, and allowance of the elected species, search and examination will continue as to the non-elected species within the scope of the generic claims.

Thus, withdrawal of the Election of Species Requirement is respectfully requested.

II. Conclusion

Entry of the foregoing and early and favorable consideration of the application are respectfully requested. Should the Examiner have any questions regarding the application, or any suggestions to expedite prosecution, the Examiner is invited to contact Applicants' undersigned attorney at the telephone number listed below.

Respectfully submitted,



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